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| APPLICATION NO.    | FILING DATE          | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|--------------------|----------------------|----------------------|------------------------------|------------------|
| 10/621,894         | 07/17/2003           | Georg Watzek         | 35931-PCT-USA-A<br>071986.02 | 1493             |
| 21003              | 7590 01/31/2005      |                      | EXAMINER                     |                  |
| BAKER &            | BOTTS<br>ELLER PLAZA | AFREMOVA, VERA       |                              |                  |
| NEW YORK, NY 10112 |                      |                      | ART UNIT                     | PAPER NUMBER     |
|                    |                      |                      | 1651                         |                  |
|                    |                      |                      |                              |                  |

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |   | Application No.  | Applicant(s)  |            |  |  |
|---|---|--|---|------------|--|--|
| Office Action Summary   |   | 10/621,894   | WATZEK ET AL.   |            |  |  |
|   |   | Examiner   | Art Unit  |            |  |  |
|   |   | Vera Afremova  | 1651  |            |  |  |
| The MAILING DATE of this of Period for Reply  | ommunication app  | ears on the cover sheet wit  | th the correspondence addre   | ss         |  |  |
| A SHORTENED STATUTORY PE THE MAILING DATE OF THIS CO - Extensions of time may be available under the after SIX (6) MONTHS from the mailing date o - If the period for reply specified above is less the - If NO period for reply is specified above, the m - Failure to reply within the set or extended perion - Any reply received by the Office later than three earned patent term adjustment. See 37 CFR | MMUNICATION.<br>provisions of 37 CFR 1.13<br>f this communication.<br>an thirty (30) days, a reply<br>aximum statutory period w<br>do for reply will, by statute,<br>e months after the mailing                   | 6(a). In no event, however, may a rewithin the statutory minimum of thirty ill apply and will expire SIX (6) MON cause the application to become AB. | ply be timely filed  (30) days will be considered timely.  THS from the mailing date of this comm  ANDONED (35 U.S.C. § 133). | unication. |  |  |
| Status  |   |  |   |            |  |  |
| 1) Responsive to communication  | on(s) filed on 17 Ju  | Iv 2003.   |   |            |  |  |
| 2a) This action is <b>FINAL</b> .   |   | action is non-final.   |   |            |  |  |
|   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |  |   |            |  |  |
| Disposition of Claims   |   |  |   |            |  |  |
| 4)  Claim(s) 1-12 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5)  Claim(s) is/are allowed.  6)  Claim(s) 12 is/are rejected.  7)  Claim(s) 4-11 is/are objected to.  8)  Claim(s) 1-12 are subject to restriction and/or election requirement.  |   |  |   |            |  |  |
| Application Papers  |   |  |   |            |  |  |
| 9) The specification is objected to by the Examiner.  |   |  |   |            |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |   |  |   |            |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |  |   |            |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |  |   |            |  |  |
| Priority under 35 U.S.C. § 119  |   |  |   |            |  |  |
| _   | ne of: priority documents priority documents copies of the priori ternational Bureau  | have been received. have been received in Apity documents have been (PCT Rule 17.2(a)).  | oplication No received in this National Sta   | nge        |  |  |
| Attachment(s)   |   | <b></b> -  |   |            |  |  |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing F</li> <li>Information Disclosure Statement(s) (PTO Paper No(s)/Mail Date</li> </ol>   |   | Paper No(s)  | ummary (PTO-413)<br>/Mail Date<br>formal Patent Application (PTO-15)<br>  | 2)         |  |  |

#### **DETAILED ACTION**

Claims 1-12 are pending and subject to restriction requirement.

#### Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-10, drawn to a drug composition comprising microparticles from blood, classified in class 435, subclass 2, for example.
- II. Claim 11, drawn to a process for promoting regeneration of bone tissues, classified in class 435, subclass 366, for example.
- III. Claim 12, drawn to a method of using aqueous suspension of blood derived microparticles for making drug composition, classified in class 424, subclass 93.72, for example.

The inventions are distinct, each from the other because of the following reasons:

The inventions are Group I and Group III are distinct because they require different components as claimed. The product of Group I is a dry composition with blood-derived microparticles that is provided in a freeze-dried form as claimed and intended for topical application as claimed. The method of making product of the Group III requires the use of aqueous suspension of blood-derived microparticles that is intended for growth of osteoblasts as claimed.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case drug with microparticles derived from blood or composition with thrombocytes can be used for treating patients with leukemia, for example: see US 5,004,604 at col. 7, lines 1-4.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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## Claim Objections

Claims 4-11 are objected to under 37 CFR 1.75(c) as being in improper form of multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims 4-11 cannot be properly further treated on the merits.

### Claim Rejections - 35 USC § 112

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 provides for the use of aqueous suspension of blood microparticles, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 12 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

January 30, 2005

**VERA AFREMOVA** 

V. Afra

PRIMARY EXAMINER

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